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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,217	04/09/2001	Toshio Hirano	205721US0CON	6439

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,217	HIRANO ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. It is noted that dependent claim 16 appears to have been intended to depend on claim 15 rather than claim 14, as recited. For the purposes of examination, the Examiner has changed the dependency of claim 16 to depend on claim 15. The Applicant is invited to clarify the dependency of claim 16.

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 11 – 16 and 18 – 20 have been renumbered 14 – 22.

In response to this office Action, the applicant is required to provide a new set of claims to reflect the correct numbering of claims.

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/01/2004 has been entered.

5. Applicant's amendment, filed 07/01/2004, is acknowledged and has been entered.

Claims 1 – 10 have been cancelled.

Claims 11 – 13, submitted 03/31/2004, have been not entered.

Claims 11 – 16 and 18 – 20 (submitted 07/01/2004), have been added, and renumbered 14 – 22.

Claims 11 – 16 and 18 – 20 (renumbered 14 – 22) are pending.

Claims 18 – 20 (renumbered 20 – 22) have been withdrawn from consideration by the Examiner as being drawn to non-elected Inventions.

Claims 14 – 19 are under consideration in the instant application.

6. Newly submitted claims 20 – 22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The Invention of the originally presented claims is drawn to an antibody which recognizes a membrane protein having pre-B cell growth supporting ability. The Invention of the newly added claims 20 – 22 is drawn to a method of identifying synovial cells or subjects having rheumatoid arthritis.

The originally presented Invention and the newly added Invention are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of the originally presented Invention can be used for affinity purification, in addition to the methods of identifying synovial cells or subjects having rheumatoid arthritis, as recited.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20 – 22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. This Office Action will be in response to applicant's arguments, filed 07/01/2004.

The rejections of record can be found in the previous Office Actions.

It is noted that New Grounds of Rejection are set forth herein.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14 – 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following *New Matter* rejection is set forth herein:

Newly added claims 14 and 118, and dependent claims 15 – 17 and 19 are drawn to "an antibody which has a positive reactivity against myeloid cells" and recognizes a polypeptide of SEQ ID NO:1.

Applicant's amendment, filed 07/01/2004, directs support to page 24, Table 1 for the written description for the above-mentioned limitations. However, the passages pointed out by the applicant do not provide support for the genus of an antibody which has positive reactivity against a genus of myeloid cells.

The data presented in Table 1 provide support for one specific antibody (RS38), and for its reactivity with four specific myeloid leukemia cell lines, but not the genus of "myeloid cells."

The specification as filed does not provide sufficient written description of this phrase. The specification does not provide sufficient blazemarks nor direction for the instant methods or products encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

The specification and the claims as originally field only support a genus of "an antibody which has a positive reactivity against certain cell lines" (page 24 Table 1). See In re Smith 173 USPQ 679, where it was ruled that a genus may not support a subgenus even though there is a disclosed species within the subgenus.

Applicant is required to cancel the New Matter in the response to this office Action.

Alternatively, applicant is invited to point to sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.05-06 and 2173.05(i).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 14 – 19 are rejected under 35 USC 102(b) as being anticipated by Goto et al. (1992, of record, see entire document), alone and in further evidence of the distribution of the RS38 antigen on various cell lines disclosed in Table 1 of the instant specification.

Goto et al. (1992) teach an antibody (HM1.24) to a protein which is identical in sequence to SEQ ID NO:1 of the instant invention.

Applicant's arguments, filed 07/01/2004, have been fully considered but were not found convincing. The rejection is maintained essentially for the reasons of record.

Applicant argues that the rejection would not apply to the new claims, because these claims require "an antibody which has a positive reactivity against myeloid cells." Applicant further asserts that a later publication by Goto et al. (1994, of record) indicates that the HM1.24 antibody (which recognizes the same antigen as the RS38 antigen of the instant invention) does not exhibit reactivity against myeloid cells, even though, as Applicant asserts, the binding experiments of both Goto et al. and the instant application were both performed by similar methods of flow cytometry.

Contrary to applicant's assertions, the data of Goto et al. (1994) show lack of reactivity of the HM1.24 antibody to particular myeloblastic leukemia and myelogenous leukemia cell lines, while the reference is silent with regard to "myeloid cells," broadly encompassed by the claimed invention.

Goto et al. teach an antibody directed to the same antigen as the RS38 antibody of the instant application. The instant application includes the following recitation regarding the distribution of the claimed antigen specificity (page 22, bottom paragraph): "The distribution of the RS38 antigen in various cell lines (various cell lines shown in Table 1)" [underlining added]. Thus this disclosure provides evidence that the data in Table 1 refer to the distribution of the target antigen in the cell lines, not just the antibody cross-reactivity. Consequently, given that the target antigen is present in the myeloid leukemia cell lines listed in Table 1, reactivity with these cell lines would be an inherent property of antibodies specifically reactive against the same antigen, including the antibodies taught by Goto et al. (1992 and 1994).

Therefore, the claimed functional limitations of positive reactivity against specific cells would be inherent properties of the antibodies taught by Goto et al. (1992) which recognize the same antigen.

10. Conclusion:

No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

July 29, 2004

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
8/23/04